New, virtually wall-less cannulas designed for augmented venous drainage in minimally invasive cardiac surgery

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Abstract: OBJECTIVE: Inadequate venous drainage during minimally invasive cardiac surgery becomes most evident when the blood trapped in the pulmonary circulation floods the surgical field. The present study was designed to assess the in vivo performance of new, thinner, virtually wall-less, venous cannulas designed for augmented venous drainage in comparison to traditional thin-wall cannulas. METHODS: Remote cannulation was realized in 5 bovine experiments (74.0 ± 2.4 kg) with percutaneous venous access over the wire, serial dilation up to 18 F and insertion of either traditional 19 F thin wall, wire-wound cannulas, or through the same access channel, new, thinner, virtually wall-less, braided cannulas designed for augmented venous drainage. A standard minimal extracorporeal circuit set with a centrifugal pump and a hollow fiber membrane oxygenator, but no in-line reservoir was used. One hundred fifty pairs of pump-flow and required pump inlet pressure values were recorded with calibrated pressure transducers and a flowmeter calibrated by a volumetric tank and timer at increasing pump speed from 1500 RPM to 3500 RPM (500-RPM increments). RESULTS: Pump flow accounted for 1.73 ± 0.85 l/min for wall-less versus 1.17 ± 0.45 l/min for thin wall at 1500 RPM, 3.91 ± 0.86 versus 3.23 ± 0.66 at 2500 RPM, 5.82 ± 1.05 versus 4.96 ± 0.81 at 3500 RPM. Pump inlet pressure accounted for 9.6 ± 9.7 mm Hg versus 4.2 ± 18.8 mm Hg for 1500 RPM, -42.4 ± 26.7 versus -123 ± 51.1 at 2500 RPM, and -126.7 ± 55.3 versus -313 ± 116.7 for 3500 RPM. CONCLUSIONS: At the well-accepted pump inlet pressure of -80 mm Hg, the new, thinner, virtually wall-less, braided cannulas provide unmatched venous drainage in vivo. Early clinical analyses have confirmed these findings.

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New, Virtually Wall-less Cannulas Designed for Augmented Venous Drainage in Minimally Invasive Cardiac Surgery

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Objective: Inadequate venous drainage during minimally invasive cardiac surgery becomes most evident when the blood trapped in the pulmonary circulation floods the surgical field. The present study was designed to assess the in vivo performance of new, thinner, virtually wall-less, venous cannulas designed for augmented venous drainage in comparison to traditional thin-wall cannulas.

Methods: Remote cannulation was realized in 5 bovine experiments (74.0 ± 2.4 kg) with percutaneous venous access over the wire, serial dilation up to 18 F and insertion of either traditional 19 F thin wall, wire-wound cannulas, or through the same access channel, new, thinner, virtually wall-less, braided cannulas designed for augmented venous drainage. A standard minimal extracorporeal circuit set with a centrifugal pump and a hollow fiber membrane oxygenator, but no in-line reservoir was used. One hundred fifty pairs of pump-flow and required pump inlet pressure values were recorded with calibrated pressure transducers and a flowmeter calibrated by a volumetric tank and timer at increasing pump speed from 1500 RPM to 3500 RPM (500-RPM increments).

Results: Pump flow accounted for 1.73 ± 0.85 l/min for wall-less versus 1.17 ± 0.45 l/min for thin wall at 1500 RPM, 3.91 ± 0.86 versus 3.23 ± 0.66 at 2500 RPM, 5.82 ± 1.05 versus 4.96 ± 0.81 at 3500 RPM. Pump inlet pressure accounted for 9.6 ± 9.7 mm Hg versus 4.2 ± 18.8 mm Hg for 1500 RPM, −42.4 ± 26.7 versus −123 ± 51.1 at 2500 RPM, and −126.7 ± 55.3 versus −313 ± 116.7 for 3500 RPM.

Conclusions: At the well-accepted pump inlet pressure of −80 mm Hg, the new, thinner, virtually wall-less, braided cannulas provide unmatched venous drainage in vivo. Early clinical analyses have confirmed these findings.

Key Words: Venous cannula, Minimally invasive cardiac surgery, MICS, Cardiopulmonary bypass, Perfusion cannulation, Venous cannula, Augmented venous drainage, Vacuum assisted venous drainage.

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Inadequate venous drainage during minimally invasive cardiac surgery (MICS) becomes most evident when the blood trapped in the pulmonary circulation floods the surgical field. This phenomenon has been described early on at the introduction of MICS when it became clear that the theoretical target flow for cardiopulmonary bypass of 2.4 l/min per m^2 could often not be reached,[1] and this despite augmented venous drainage by either a centrifugal pump or vacuum in combination with well-positioned conventional percutaneous cannulas[2] designed for remote cannulation.[3,4] Based on our experience with covered stent-grafts for endovascular aneurysm repair,[5] we developed a remote cannulation system that allowed for collapsed cannula insertion and re-expansion in situ, thus taking advantage of the diameter increase of affluent cardiac veins from the periphery toward the right atrium. The diameter of the common femoral vein in adult patients typically measures 8 ± 1 mm and therefore accepts usually a 21-F to 27-F percutaneous cannulas. The original self-expanding cannulas[6] have a nominal diameter of 36 F, but pass through a 24 F orifice, fit easily with all venous access diameters from 24 F to 36 F, and are efficient enough to provide full flow with gravity drainage alone. Although the 36 F self-expanding cannulas have been successfully used with peripheral percutaneous access and gravity drainage including MICS,[7] it became evident that smaller-diameter designs might eventually work in combination with augmented venous drainage. After various studies in silico[8] and in vitro,[9,10] it seemed that thinner 24-F self-expanding, virtually wall-less cannulas designed for augmented venous drainage seemed to function well in combination with a centrifugal pump. The present study was designed to assess the in vivo performance of these new thinner, virtually wall-less, venous cannulas designed for augmented venous drainage in comparison to traditional thin-wall cannulas.

MATERIALS AND METHODS

Five bovine experiments (bodyweight, 74.0 ± 2.4 kg) were realized after approval of the protocol by the State Veterinary Office (Authorization No. 1068.6) with general anesthesia in routine fashion (premedication with atropin and xylazine, intubation with propofol, maintenance with isoflurane and fentanyl). Electrocardiogram, central venous pressure, aortic pressure, and percutaneous oxygen saturation were monitored continuously. Whereas a small cut down was used for carotid artery cannulation with a ¼-inch 16 F 220 arterial Smartcanula (Smartcanula

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LLC, Lausanne, Switzerland), remote cannulation of the caval axis through the external jugular vein was realized with percutaneous venous access over the wire using a 18 G hollow needle and a 0.035-inch guide wire, serial dilation up to 18 F with step dilators (8/10 F, 12/14 F, 16/18 F: Smart Dilator Set, Smartcanula LLC, Lausanne, Switzerland) and insertion of either a traditional 19-F thin wall, wire-wound control cannula (Biomedicus, Medtronic, Inc, Minneapolis, MN USA) or through the same 19 F access channel, a new, smaller 24 F, virtually wall-less, braided cannula (Fig. 1) designed for augmented venous drainage (Smartcanula 3/8, 24 F, 630 stiff (ST), Smartcanula LLC, Lausanne, Switzerland). A standard minimal extracorporeal circuit (MECC) set with a centrifugal pump and a hollow fiber membrane oxygenator, but no in-line reservoir was used. One hundred fifty pairs of pump-flow and required pump inlet pressure values were recorded with calibrated pressure transducers and a flowmeter calibrated by a volumetric tank and timer at increasing pump speed [revolutions per minute (RPM)] from 1500 RPM to 3500 RPM (500-RPM increments).

RESULTS

The RPM of the centrifugal pump flow relationship is shown in Figure 2. Pump flow accounted for 1.73 ± 0.85 L/min for wall-less versus 1.17 ± 0.452 L/min for thin wall at 1500 RPM, 3.91 ± 0.86 versus 3.23 ± 0.66 at 2500 RPM, 5.82 ± 1.05 versus 4.96 ± 0.81 at 3500 RPM. Pump inlet pressure is displayed in Figure 3 and accounted for 9.6 ± 9.7 mm Hg versus 4.2 ± 18.8 mm Hg at 1500 RPM, −42.4 ± 26.7 versus −123 ± 51.1 at 2500 RPM, and −126.7 ± 55.3 versus −313 ± 116.7 at 3500 RPM. The pump flow–pump inlet pressure relationship is shown in Figure 4. There is a significant difference between the new, smaller virtually wall-less, venous cannulas designed for augmented venous drainage and the traditional thin wall cannulas used as controls ($P = 0.027$). At 2500 RPM, the traditional thin wall cannula drains 3.2 ± 0.7 L/min at −123 ± 51 mm Hg, whereas the new, virtually wall-less design drains 3.9 ± 0.9 L/min at −42 ± 27 mm Hg.

FIGURE 1. Demonstration of the configuration of the thinner, virtually wall-less cannula family designed for augmented venous drainage: Ref. 3/8" 24 F 260 mm ST (Smartcanula LLC, Lausanne, Switzerland). The device connects to 3/8" (left), has a 24 F covered section passing through a 20-F access orifice (center), and an uncovered virtually wall-less section for unrestricted drainage at all levels of the caval axis (right). The 24 F ST family designed for augmented venous drainage in adults is available in lengths ranging from 200 mm to 800 mm. As the connecting section and the covered section are the same for all configurations, the uncovered section available for drainage varies in length from 40 mm to 640 mm. The most frequently used length in the clinical setting is the 630 mm version, which was also tested in this study.

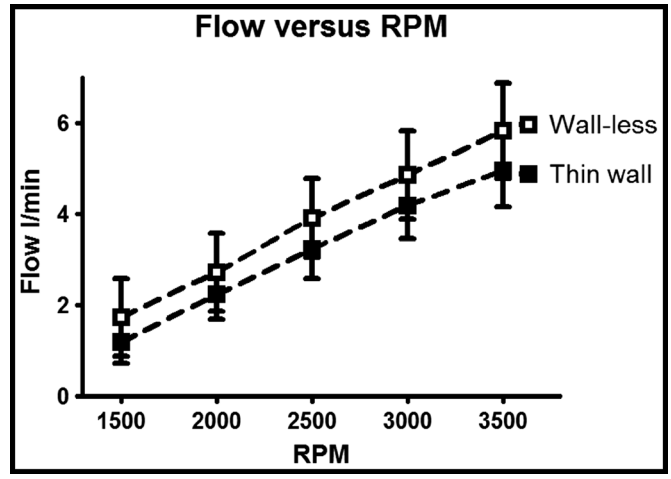

FIGURE 2. Centrifugal pump revolutions per minute (RPM) versus flow achieved (L/min) in vivo: consistently higher flows are observed for the new, thinner, virtually wall-less cannula design compared to the traditional thin-wall control.

DISCUSSION

The new, smaller, virtually wall-less, self-expanding cannula designed for augmented venous drainage outperforms in vivo the traditional percutaneous cannulas for both key performance parameters in the clinical setting, which are flow and required augmentation at all tested RPMs. For a clinical scenario with a 74-kg adult patient, a flow at 2500 RPM of 3.9 ± 0.9 L/min reached with the new thinner wall-less design

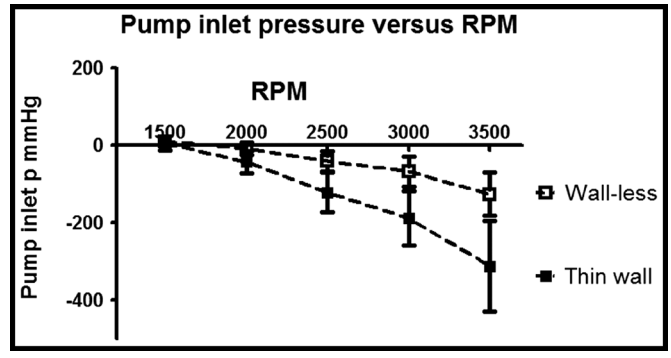

FIGURE 3. Centrifugal pump RPM versus negative pressure developed at the pump inlet (mm Hg) in vivo: consistently lower pressures are observed for the new, thinner, virtually wall-less cannula design compared to the traditional thin-wall control.

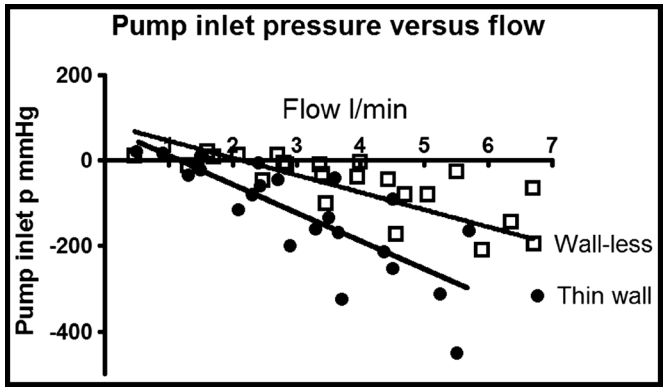

FIGURE 4. Flow achieved (L/min) versus required negative pump inlet pressure in vivo: significantly lower, more physiologic pump inlet pressures (mm Hg) are required to provide consistently higher flows (L/min) for the new, thinner, virtually wall-less cannula design compared to the traditional thin-wall control.

at −42 ± 27 mm Hg is a very good performance considering the 19-F access percutaneous tunnel. In contrast, the 3.2 ± 0.7 L/min reached with the traditional percutaneous cannula is certainly below the requirements for perfusion of a 74-kg adult patient, and the fact that an augmentation of −123 ± 51 mm Hg was required makes the situation even worse considering the maximal acceptable augmentation in clinical practice is −80 mm Hg.

It has been recognized a long time ago[2] that perfusion with remote cannulation is a challenge, especially if the target is to provide full flow defined as 2.4 L/min/m^2 in all patients. Actually, this goal can be reached by remote venous cannulation relatively easily in patients with large femoral veins accepting a traditional 27 F thin wall venous cannula in combination with augmented venous drainage. However, the mean diameter of the common femoral vein is rather 8 ± 1 mm (personal experience, 9) and therefore, the anatomically accepted outer venous cannula diameter is more frequently 24 F or 21 F and sometimes even less. We have previously reported our experience with self-expanding cannulas designed for gravity drainage in general[6] and more specifically for MICS.[7] We found that the configuration with a nominal diameter of 36 F, which can be inserted through a 24 F access orifice provides full flow at negative pressure loads of less than 50 mm Hg.[6,7] However, current clinical practice in MICS is to run for venous drainage augmentations of up to 80 mm Hg,[2–4,11,12] and under these conditions, it seemed worthwhile to design a smaller virtually wall-less cannula, taking advantage of the higher augmentation used in clinical routine for this setting. Following positive results during in silico and in vitro evaluation of this new thinner 24 F ST design with increased hoop strength,[13,14] the present study was realized for in vivo validation and confirmed the benefit of this approach. There are a number of reasons that can explain the performance increase of the virtually wall-less cannula designs compared to traditional thin-wall percutaneous cannulas including the following:

- The larger mean cross-sectional diameter of the self-expanding design, which is due to the collapsed-insertion and expansion in situ approach, thus achieving an intravascular diameter above the access channel diameter, a feature, which by definition cannot be reached with traditional rectilinear cannulas
- The reduced wall thickness of the virtually wall-less design, which measures typically less than 0.5 mm wherever there is a cannula wall like in the access channel compared to more than 0.5 mm for the typical thin wall cannula
- The total area of cannula orifices, which is at least one order of magnitude higher (= almost the entire intravascular cannula surface) than the one of a typical thin wall cannula (= somewhat above the cross-sectional area)
- The virtually wall-less design allowing for direct drainage of blood at all levels of affluent veins compared to complex flow paths along a traditional thin wall cannula first and inside that same cannula second
- The temporary caval stenting function of the virtually wall-less design that allows to keep the drained vessel open over the entire cannula length, and thus contributes to the finding previously reported that longer virtually wall-less cannulas provide better drainage in the experimental[15] as well as the clinical setting.[6]

As a result of the improved performance, a single virtually wall-less cannula is sufficient for full flow, and dual cannulation with an additional jugular venous cannula is not necessary in cases where the right side of the heart is not opened like in MICS[16] and even in some situations with open right side including the Ross procedure for harvesting the pulmonary valve and reconstruction of the pulmonary outflow tract (personal experience), tricuspid valve repair and replacement,[17] etc.

A further important aspect is the significantly lower negative pressures required for full flow in combination with virtually wall-less cannula designs per se compared to conventional thin-wall percutaneous cannulas. As a matter of fact, it has been demonstrated early on that augmented venous drainage with either vacuum or a centrifugal pump (also called kinetic assistance) increases the load of microemboli on the arterial side in vitro.[18,19] However, at negative pressures up to −40 mm Hg, there was no difference compared to drainage by gravity.[20] Similar reports are available for the clinical setting,[21] where not only additional gaseous embolic load but also excessive hemolysis are an issue,[21] a phenomenon being also known for a long time.[22] This latter concern has proven to be unfounded for the stent-type design of the virtually wall-less cannulas studied here as demonstrated previously for its use in combination with gravity drainage[6,23] as well as with augmented venous drainage.[24]

We conclude that there are physical (larger mean cannula diameter, thinner wall, and virtually wall-less design), anatomical (larger mean diameter of the drained vessel), physiologic (direct drainage of affluent venous blood), and strategic (temporary caval stenting over a longer distance) reasons that explain why the new, thinner, virtually wall-less venous cannulas with increased hoop strength provide unmatched venous drainage in vivo at lower negative pressure. Early clinical analyses confirm these findings.

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CLINICAL PERSPECTIVE

Venous drainage can often be a problem during minimally invasive cardiac surgery. There have been few advances in cannula design over the past decade. This study from Dr. von Segesser and his colleagues examined the in vivo performance in 5 animals of new, thinner, virtually wall-less venous cannulas designed for augmented venous drainage. At a set revolutions per minute, pump flow was higher in the wall-less cannulae compared to the more traditional thin-wall design. Moreover, excellent pump flow could be obtained at a much lower negative pressure for venous drainage augmentation.

This is an elegant study, which documented the improved performance of these virtually wall-less cannula designs. This would likely obviate the need for ever placing a second venous cannula during minimally invasive cardiac procedures. Clinical studies will be needed to confirm these findings, but these are clearly promising experimental results. This is an area sorely in need of innovation, and the authors are to be congratulated on developing this facilitative technology.